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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,052	04/14/2004	Hosheng Tu	GLAUKO.1CP1C1	6106

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EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
08/08/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/824,052	TU ET AL.	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *5 and 7-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6 and 12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 March 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/9/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Claim 6 in the reply filed on 6/26/07 is acknowledged. Claims 1 and 7-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/26/07.

Response to Amendment

2. In the amendment filed 3/5/07, applicant amended claim 1 and added new claims 2-17. Claims 5 and 7-11 are withdrawn, and claims 1-17 are currently pending.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-3 and 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Ahmed (US 6,261,256).

With respect to Claims 1-3, Ahmed discloses a medical device for treating glaucoma comprising an inlet section 18, an outlet section 8, and a middle section therebetween. The valve comprises a plurality of lumens (90, 92, 94, 96, and 98) that transmit aqueous humor within the device. The outlet section is disposed perpendicularly to the rest of the device, as shown in Figure 1. The device comprises a valve 10 that acts as a flow-restrictor.

With respect to Claims 14 and 15, the outlet portion of the device comprises an enlarged plate, which acts as a stabilizing member for stabilizing the glaucoma device within the eye.

With respect to Claim 16, Ahmed discloses that the device is made of a material that will not be rejected by the body, such as polypropylene or polymethyl-methylacrelate (PMMA) (Column 6, Lines 18-23).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-4, 6, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stegmann (US 5,486,165) in view of Avery et al. (US 5,725,493).

Stegman discloses a flow-regulating implant comprising an inlet section, an outlet section, and a middle section therebetween. The device is capable of being implanted into the anterior chamber of the eye and capable of being positioned such that the outlet

section is disposed with Schlemm's canal (a natural aqueous humor outflow space). The outlet is substantially perpendicular to the middle section. Stegmann, however, does not disclose that the implant comprises at least two lumens for transmitting aqueous humor within the glaucoma device, nor does it disclose the use of a filter within at lease one lumen. Avery et al. (hereafter Avery) discloses an ocular shunt comprising a filtering means made of a porous cellulose material (Column 5, Lines 51-65). The filter inherently resists flow within the shunt, as per Claim 12. Furthermore, because the filter is porous, it creates a plurality of lumens within the tube, as per Claim 1. The use of cellulose filters in ocular shunts is established in the art and prevents particulate materials, such as biodegradable polymer from passing out of the reservoir and into the body. Therefore, it would have been obvious to one of ordinary skill in the art to modify the ocular shunt of Stegmann with the porous cellulose filter of Avery in order to prevent particulate matter that may be present in the shunt from being passed into Schlemm's canal.

7. Claims 1-4, 6, 12, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ungerleider (US 4,936,825) in view of Avery (US 5,725,493).

With respect to Claims 1-4, 6, 12, 14, 15, and 17, Ungerleider discloses an ocular implant comprising an inlet section , an outlet section, and a middle section therebetween (see Figure 9). The device is capable of being implanted into the anterior chamber of the eye and positioned within a space of aqueous humor outflow in the eye. The outlet is substantially perpendicular to the middle section, and the inlet and middle

sections have a skewed relationship, as per Claim 17. The inflow and outflow sections comprise stabilizing members (19, 21) for stabilizing the device within the eye. With respect to Claim 16, Ungerleider discloses that the implant may be manufactured of a polymer material, for example polyesters, polyurethanes, or polystyrenes (Column 3, Lines 50-66). Ungerleider, however, does not disclose that the implant comprises at least two lumens for transmitting aqueous humor within the glaucoma device, nor does it disclose the use of a filter within at lease one lumen.

Avery discloses an ocular shunt comprising a filtering means made of a porous cellulose material (Column 5, Lines 51-65). The filter inherently resists flow within the shunt, as per Claim 12. Furthermore, because the filter is porous, it creates a plurality of lumens within the tube, as per Claim 1. The use of cellulose filters in ocular shunts is established in the art and prevents particulate materials, such as biodegradable polymer from passing out of the reservoir and into the body. Therefore, it would have been obvious to one of ordinary skill in the art to modify the ocular shunt of Stegmann with the porous cellulose filter of Avery in order to prevent particulate matter that may be present in the shunt from being passed into Schlemm's canal.

Response to Arguments

8. Applicant's arguments, see pages 10 and 11 of the response filed 3/5/07, with respect to the rejection(s) of claim(s) 1 under U.S.C. 102(e) in view of Hill, Savage, and Lynch have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. The priority dates of Hill and Savage fail to meet applicant's priority

date of 4/14/00. Furthermore, Lynch does not disclose the dual-lumen glaucoma shunt of Figure 1E in the provisional filing. Applicant's parent case (US 6,638,239) teaches the use of a seton implant having a plurality of lumens (Column 9, Lines 5-6).

However, upon further consideration, a new ground(s) of rejection is made in view of newly discovered prior art.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
7/19/07

LOAN H. THANH
PRIMARY EXAMINER